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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,997	09/05/2003	Andreas Caduff	24334-003	1746
30623	7590 , 12/08/200	6	EXAM	INER
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY		SINES, BRIAN J		
AND POPEC ONE FINAN	), P.C. CIAL CENTER		ART UNIT	PAPER NUMBER
BOSTON, M	ON, MA 02111 1743			
		·	DATE MAILED: 12/08/200	6

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/656,997	CADUFF ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brian J. Sines	1743				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the o	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  (6(a). In no event, however, may a reply be tirged in the second will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).				
Status		<i></i>				
1) Responsive to communication(s) filed on 22 Au	iaust 2006.					
• • • • • • • • • • • • • • • • • • • •	action is non-final.					
<i>,</i>	<u>'</u>					
closed in accordance with the practice under E		•				
Disposition of Claims						
•						
4) Claim(s) <u>1-32</u> is/are pending in the application.	withdrawa from consideration					
·	4a) Of the above claim(s) <u>1-11 and 29-31</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>12-28</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner	•.					
10) ☐ The drawing(s) filed on is/are: a) ☐ acce	epted or b) objected to by the	Examiner.				
Applicant may not request that any objection to the o	frawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign	priority under 35 H S C & 110/a	\-(d) or (f)				
a) All b) Some * c) None of:	priority under 33 0.3.0. § 119(a	)-(d) 01 (1).				
1. ☐ Certified copies of the priority documents	have been received					
2. Certified copies of the priority documents		ion No				
	• •					
	·	ed III tills National Stage				
application from the International Bureau	* **	ad.				
* See the attached detailed Office action for a list of	or the certified copies not receive	ea.				
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
Paper No(s)/Mail Date  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO/SB/08)  Notice of Informal Patent Application						
Paper No(s)/Mail Date	6) Other:					
Patent and Trademark Office						

Art Unit: 1743

## **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of group II comprising claims 12 - 28 in the reply filed on 8/22/2006 is acknowledged. Claims 1 - 11 and 29 - 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

# **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 – 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 15 of copending Application No. 09/980,661 to Schrepfer et al. in view of Kifune (U.S. Pat. No. 4,445,885). This is a provisional obviousness-type double patenting rejection.

Art Unit: 1743

Regarding claim 12 of the this application, Schrepfer et al. in claim 1 of the copending application recites a methodology comprising the similar steps of:

arranging a first electrode at said specimen, wherein said first electrode is electrically insulated from the specimen;

applying a modulated electrical voltage to the first electrode for generating a modulated field in the specimen;

measuring at least one parameter depending on a response of the specimen to the field; and

determining the concentration therefrom.

Schrepfer et al. do not claim the further step of controlling an aspect of the process (e.g., an insulin injection) based at least in part on the determined concentration (e.g., glucose concentration) in a living body.

The linking of a glucose concentration determination means and an insulin pumping means for administering insulin medication to a patient is desirable and well known in the art (see MPEP § 2144.03). For example, Schrepfer et al. teaches that the invention also be used in devices that-automatically administer medication to a body, such as an insulin pump, where the amount and/or time for administering the medication depends on the measured concentration. It can also be used in any other type of device that requires the measurement of the concentration of a substance in body fluid (see paragraph 52). In addition, Kifune also teaches the combining of a glucose sensor with an insulin injunction means (see, e.g., col. 1, line 1 – col. 2, line 42). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating a method step for controlling an aspect of a process (e.g., insulin

Art Unit: 1743

injection) based at least in part on the determined glucose concentration. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a method step for controlling an aspect of a process (e.g., insulin injection) based at least in part on the determined glucose concentration.

Regarding claim 13, Kifune further teaches the incorporation of a valve control for facilitating injection control with the disclosed apparatus and associated method (see, e.g., col. 5, lines 48-68).

Regarding claim 14 of this application, Schrepfer et al. in claim 2 of the copending application recites that a modulated electrical voltage is applied between the first and second electrodes.

Regarding claim 15 of this application, Schrepfer et al. in claim 3 of the copending application recites that the second electrode is in electric contact with the specimen comprising a body liquid.

Regarding claim 16 of this application, Schrepfer et al. in claim 4 of the copending application recites the step of measuring a temperature of the specimen and using the temperature in the determination of the specimen.

Regarding claim 17 of this application, Schrepfer et al. in claim 5 of the copending application recites that the modulated electrical voltage signal is a sine wave.

Regarding claim 18 of this application, Schrepfer et al. in claim 6 of the copending application recites that the modulated electrical voltage signal has a frequency between 10 MHz and 2 GHz.

Art Unit: 1743

Regarding claim 19 of this application, Schrepfer et al. in claim 9 of the copending application recites the use of an antennae electrode.

Regarding claim 20 of this application, Schrepfer et al. in claim 10 of the copending application recites the use of an antennae electrode.

Regarding claim 21 of this application, Schrepfer et al. in claim 11 of the copending application recites the use of a living body.

Regarding claim 22 of this application, Schrepfer et al. in claim 12 of the copending application recites the use of calibration data.

Regarding claim 23 of this application, Schrepfer et al. in claim 13 of the copending application recites the use of a resonant circuit and an operating resonance frequency.

Regarding claim 24 of this application, Schrepfer et al. in claim 14 of the copending application recites the use of a tank circuit of an active oscillator employing the use of an amplitude and an oscillator generated signal frequency.

Regarding claim 25 of this application, Schrepfer et al. in claim 15 of the copending application recites the use of a frequency sweep.

Regarding claim 26, the use of control methods for industrial fermentation processes are well known in the art (see MPEP § 2144.03). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of alcohol as a measured parameter in controlling the fermentation process.

Regarding claims 27 and 28, Schrepfer teaches the use of salt solutions (see paragraph 31). Furthermore, it is well known in the art that body fluids comprise various components, such

Art Unit: 1743

as salt and salt solutions (e.g., solvated sodium, potassium, chloride and calcium solutions) (see MPEP § 2144.03)

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines

Primary Examiner

Art Unit 1743